

**REMARKS**

This paper is in response to the Final Office Action dated September 24, 2003. Claims 1-13 and 17-22 are pending. All the pending claims stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,261,271 to Solomon et al. ("Solomon") alone and/or over Solomon further in view of the Merck Index.

The Office Action also reiterates the rejection of claims 1-2, 8-9, 17, and 21-22 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of co-pending Application No. 09/746,658. Applicants again respectfully traverse this rejection until such time as a claim in the instant application is allowed.

For reasons set forth below, Applicants respectfully request that the rejections be removed and the claims be allowed to issue.

**The claimed invention is not obvious over Solomon**

Quoting verbatim from the abstract and specification of Solomon, the Office Action states that Solomon discloses an anti-infective medical article which is made of a polymer wherein chlorhexidine is bulk distributed throughout the polymer. The Office Action also states that the polymer may further be coated with chlorhexidine. The Office Action then admits that Solomon fails to disclose the weight/weight ratio of chlorhexidine free base and water-soluble chlorhexidine salt in solution between 1:1 to 1:5 percent, as required by the pending claims of the instant application, but states: "Absent unexpected results, it is the position of the examiner [that] it would have been

obvious to one of ordinary skill in the art at the time the invention was made to have determined a suitable % weight of the chlorhexidine free base and water-soluble chlorhexidine salt” when coating a medical article according to Solomon’s teachings. Applicants respectfully disagree with this analysis and conclusion.

The claimed invention is directed to a medical article that is treated with a solution consisting essentially of a 1:1 to 1:5 mixture of chlorhexidine free base and chlorhexidine salt, in addition to solvent. The Office Action asserts that Solomon teaches the claimed invention because it discloses the use of a mixture of chlorhexidine free base and salt that is bulk distributed throughout the polymer from which the medical article is made. That analysis overlooks, however, that Solomon’s further coating of chlorhexidine is not taught to be a mixture of chlorhexidine free base and chlorhexidine salt, and is not taught to be effective independent of the polymer having chlorhexidine bulk distributed throughout. (“The extruded article may be steeped in a solution of chlorhexidine to provide the article with additional chlorhexidine as a coating permeated into the surface of the article.” Solomon at col. 2, ll. 45-48 (emphasis added); “The preferred article additionally has a layer of chlorhexidine, preferably a chlorhexidine salt, permeated into the surface of the article.” Solomon at col. 3, ll. 6-8).

Notably, the specification teaches that the bulk distributed chlorhexidine “may be either in the form of the free base or, preferably in the form of a salt such as the hydrochloride, acetate and gluconate.” (Solomon at col. 3, ll. 1-3) (emphasis added). Directed specifically to the optional chlorhexidine coating, the specification states: “The preferred article additionally has a layer of chlorhexidine, preferably a chlorhexidine salt, permeated into the surface of the article.” (Solomon at col. 3, ll. 6-8). The specification

is tellingly silent with respect to mixtures of chlorhexidine free base and salt. In fact, the only teaching by Solomon related to the use of a mixture of chlorhexidine free base and salt may be found in the claims (i.e., claims 16 and 39), and this claimed use is related only to chlorhexidine that is bulk distributed throughout the polymer from which the medical article is made. Thus, nowhere does Solomon state that its further coating may contain a mixture of chlorhexidine free base and salt.

As such, when considered as a whole, Solomon fails to disclose, teach or suggest a medical article that is treated with a solution of chlorhexidine free base and chlorhexidine salt. On the contrary, by setting forth its preferred embodiment of the additional chlorhexidine layer as a chlorhexidine salt alone (“The preferred article additionally has a layer of chlorhexidine, preferably a chlorhexidine salt, permeated into the surface of the article.” Solomon at col. 3, ll. 6-8), Solomon actually teaches away from treating a medical article with a solution of chlorhexidine free base and chlorhexidine salt. Indeed, the preferred embodiment is testament to Solomon’s lack of appreciation of the synergy between chlorhexidine free base and chlorhexidine salt as an antimicrobial agent.

Furthermore, and in direct contrast to Solomon, the presently claimed medical articles do not require having chlorhexidine bulk distributed throughout the polymer. Indeed, the instant specification distinguishes bulk distributed chlorhexidine from the claimed invention in that bulk distributed manufacturing methods adversely affect certain characteristics (*e.g.*, tensile strength) of the medical article, and the high temperatures involved in such methods may reduce the specific activity of the bulk distributed chlorhexidine (*see* instant specification at page 3, lines 3-7).

The above considerations, among others, manifestly undermine any assertion that an article having chlorhexidine bulk distributed throughout teaches the claimed invention, or that the skilled artisan would have been motivated to modify Solomon's teachings so as to use an additional chlorhexidine layer containing chlorhexidine free base and chlorhexidine salt. In fact, the sole motivation to treat a medical article with a solution of chlorhexidine free base and salt would be to benefit from the resulting enhanced chlorhexidine incorporation, a technical advantage which was unknown prior to Applicants' discovery of it and therefore absent in the prior art. Accordingly, withdrawal of the rejection of Claims 1-3, 8-13 and 17-22 under 35 U.S.C. § 103(a) is respectfully requested.

**The invention is not obvious over the combination of Solomon and the Merck Index**

Claims 1-13 and 17-22 also stand rejected under 35 U.S.C. 103(a) as allegedly obvious over Solomon in further view of the MERCK Index. In particular, the Office Action alleges that Solomon teaches an anti-infective medical article having chlorhexidine bulk distributed throughout and, optionally, an additional coating layer of chlorhexidine, but admits that Solomon fails to disclose the use of tetrahydrofuran as a solvent. Nevertheless, the Office Action concludes that it would have been obvious to a person of ordinary skill on art to combine the disclosures of Solomon and the MERCK Index, which among thousands of potential solvents listed therein, contains information on tetrahydrofuran (Office Action at pages 4-5). Applicants respectfully disagree with this conclusion.

Three basic criteria must be met in order to establish a *prima facie* case of obviousness. First, there must be a suggestion or motivation to modify the references or

combine the reference teachings. The fact that references can be combined does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990); *see also* M.P.E.P. § 2143. Second, there must be a reasonable expectation of success. *In re Merck*, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, all claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Only if all three of these requirements are demonstrated has a *prima facie* case of obviousness been established.

Applicants assert that the Office Action fails to establish a *prima facie* case of obviousness because it does not meet the first and third elements of the test. First, nowhere does either Solomon or the Merck Index provide the motivation to make the proposed combination of the two references. The Office Action admits as much by not finding any such motivation within the references themselves. Rather, the Office Action simply states: “Absent unexpected results, it would have been obvious to one of ordinary skill in the art [at] the time the invention was made to have modified the composition of Solomon by adding tetrahydrofuran taught by the Merck Index with the solvents taught by Solomon, because tetrahydrofuran [is] a known solvent used for polymers and is miscible with water and alcohols as taught by the Merck Index.” Office Action at page 5. As with the rejection of the claims over Solomon alone, the Office Action improperly focuses on a requirement for unexpected results, and skirts the requirement for a motivation to combine based on articulated, factual findings.

Instead, the Office Action merely concludes that the prior art can be modified in a manner that would have been obvious to person of ordinary skill in the art

at the time the claimed invention was made. Such a statement, however, is plainly insufficient to establish a prima facie case of obviousness absent some objective reason to combine the prior art teachings. *In re Lee*, 277 F.3d 1338, 1342-44, 61 U.S.P.Q.2d 1430, 1433-34 (Fed. Cir. 2002) (emphasizing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1325, 50 U.S.P.Q.2d 1161, 1171 (Fed. Cir. 1999) (the level of skill in the art cannot be relied upon to provide the suggestion to combine references); *see also* M.P.E.P. §2143.01.

Moreover, as discussed above, the primary reference relied upon (*i.e.*, Solomon) fails to teach the use of a mixture of chlorhexidine free base and chlorhexidine salt, apart from having such a mixture bulk distributed throughout a medical article. Thus, even if combined as proposed, the cited references do not meet all the limitations of the instant claims. As such, neither alone nor in combination, can Solomon teach or suggest a medical article that is treated with a mixture of chlorhexidine free base and chlorhexidine salt in a solvent.

Thus, Applicants reiterate that, when taken as a whole, the cited references do not provide the motivation to arrive at the claimed medical article which is treated with a mixture of chlorhexidine free base and chlorhexidine salt. Accordingly, withdrawal of the rejection of Claims 1-13 and 17-22 under 35 U.S.C. § 103(a) is respectfully requested.

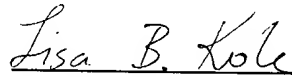
**Conclusion**

Applicants respectfully request reconsideration of the application, and entry of the foregoing remarks into the file history of the above-identified application. Applicants believe that in light of the foregoing remarks, the claims are in condition for allowance, and accordingly, respectfully request withdrawal of the outstanding rejections. An allowance is earnestly sought.

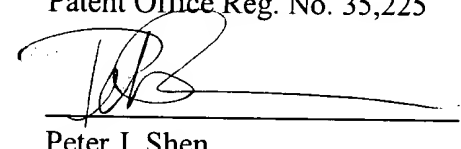
Respectfully submitted,

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